

PHARMACY SITE FILE CHECKLIST

SITE NAME:				
PSF – DOCUMENT VERSION CHECKLIST				
Complete 'yes' or 'no' to confirm the presence or absence of each document specified.				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
1. TRIAL MANAGEMENT				
CTC Contact List	14	24/11/2022	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	13	15/09/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	12	14/03/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	11	06/09/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	10	22/09/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	9	07/02/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	8	29/07/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	7	29/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	6	24/02/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	5	03/09/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	4	18/02/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	3	05/02/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	2	29/02/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
CTC Contact List (<i>superseded</i>)	1	19/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
2. SITE INFORMATION/SITE STAFF INFORMATION				
Site Staff Delegation Log	2.1	20/12/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Staff Delegation Log (<i>superseded</i>)	2	16/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Staff Delegation Log (<i>superseded</i>)	1	19/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Contact Form	4	14/01/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Contact Form (<i>superseded</i>)	3	14/11/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Contact Form (<i>superseded</i>)	2	08/03/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Contact Form (<i>superseded</i>)	1	14/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
Staff CV and details of GCP training	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	Or File Note of location
3. AGREEMENTS AND CONTRACTS				
CTSA (and Amendments, if applicable)	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Registration Form	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Summary Form	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Activation Letter	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
4. ETHICS AND REGULATORY				
Sponsorship Letter	n/a	25/06/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Insurance Letter	n/a	11/01/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Initial – CTA Approval Letter	Initial	21/09/2010	Y <input type="checkbox"/> N <input type="checkbox"/>	
Initial – REC Approval Letter	Initial	17/09/2010	Y <input type="checkbox"/> N <input type="checkbox"/>	
Initial – REC Approval Letter	Initial	11/10/2010	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#1 – REC, Cover Letter	n/a	17/01/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#1 – REC, Approval Letter	n/a	24/01/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#2 – REC, Cover Letter	n/a	01/03/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#2 – REC, Cover Letter	n/a	16/03/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#2 – REC, Approval Letter	n/a	11/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#3 – REC, Cover Letter	n/a	11/05/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#3 – REC, Approval Letter	n/a	20/05/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#4 – MHRA, Cover Letter	n/a	20/06/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#4 – MHRA, Approval Letter	n/a	26/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#5 – REC, Cover Letter	n/a	11/07/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#5 – REC, Approval Letter oval letter	n/a	17/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	

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<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
SA#6 – REC, Cover Letter	n/a	30/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#6 – REC, Approval Letter	n/a	27/09/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#7 – REC, Cover Letter	n/a	02/09/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#7 – REC, Approval Letter	n/a	27/09/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#8 – REC, Cover Letter	n/a	30/09/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#8 – REC, Approval Letter	n/a	11/10/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#9 – REC, Cover Letter	n/a	22/12/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#9 – REC, Approval Letter	n/a	24/01/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#9 – MHRA, Cover Letter	n/a	09/12/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#9 – MHRA, Approval Letter	n/a	31/01/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#10 – REC, Cover Letter	n/a	09/02/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#10 – REC, Approval Letter	n/a	30/03/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#11 – REC, Cover Letter	n/a	02/04/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#11 – REC, Approval Letter	n/a	09/05/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#12 – REC, Cover Letter	n/a	26/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#12 – REC, Approval Letter	n/a	01/08/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – REC, Cover Letter	n/a	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – REC, Unfavourable Opinion Letter	n/a	17/08/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – REC, Approval Letter	n/a	25/10/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – MHRA, Cover Letter	n/a	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – MHRA, Approval Letter	n/a	06/09/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#13 – USM Letter to Investigators	n/a	24/09/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#14 – REC, Cover Letter	n/a	19/10/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#14 – REC, Approval Letter	n/a	29/10/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#15 – REC, Cover Letter	n/a	04/01/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#15 – REC, Approval Letter	n/a	15/01/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#16a – REC, Cover Letter	n/a	29/01/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#16a – REC, Approval Letter	n/a	31/01/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#16b – REC, Cover Letter	n/a	15/05/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#16b – REC, Approval Letter	n/a	21/05/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#17 – REC, Cover Letter	n/a	04/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#17 – REC, Approval Letter	n/a	13/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#18 – REC, Cover Letter	n/a	17/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#18 – REC, Approval Letter	n/a	09/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#18 – MHRA, Cover Letter	n/a	18/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#18 – MHRA, Approval Letter	n/a	23/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#19 – REC, Cover Letter	n/a	15/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#19 – REC, Approval Letter	n/a	30/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#20 – REC, Cover Letter	n/a	20/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#20 – REC, Approval Letter	n/a	25/09/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#21 – REC, Cover Letter	n/a	26/11/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#21 – REC, Approval Letter	n/a	29/11/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#22 – REC, Cover Letter	n/a	27/01/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#22 – REC, Approval Letter	n/a	30/01/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#23 – REC, Cover Letter	n/a	01/04/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#23 – REC, Approval Letter	n/a	17/04/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#24 – REC, Cover Letter	n/a	28/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites.</i>

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SA#24 – REC, Approval Letter	n/a	29/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	Refer to Amendment Log for details.
SA#25 – REC, Cover Letter	n/a	10/07/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#25 – REC, Approval Letter	n/a	16/07/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#26 – REC, Cover Letter	n/a	08/10/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#26 – REC, Approval Letter	n/a	09/10/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#27 – REC, Cover Letter	n/a	31/10/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#27 – REC, Approval Letter	n/a	14/11/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#28 – MHRA, Cover Letter	n/a	26/01/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#28 – MHRA, Approval Letter	n/a	12/02/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#29 – REC, Cover Letter	n/a	17/02/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#29 – REC, Approval Letter	n/a	26/02/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#30 – REC, Cover Letter	n/a	12/03/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#30 – REC, Approval Letter	n/a	16/03/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#31 – REC, Cover Letter	n/a	24/03/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#31 – REC, Approval Letter	n/a	31/03/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#32 – REC, Cover Letter	n/a	01/05/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#32 – REC, Approval Letter	n/a	08/05/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#33 – REC, Cover Letter	n/a	12/06/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#33 – REC, Approval Letter	n/a	18/06/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#34 – REC, Cover Letter	n/a	31/07/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#34 – REC, Approval Letter	n/a	11/08/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#34 – MHRA, Cover Letter	n/a	31/07/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#34 – MHRA, Approval Letter	n/a	08/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#35 – REC, Cover Letter	n/a	22/12/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#35 – REC, Approval Letter	n/a	04/01/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#35 – MHRA, Cover Letter	n/a	22/12/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#35 – MHRA, Approval Letter	n/a	01/02/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#36 – REC, Cover Letter	n/a	26/02/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#36 – REC, Approval Letter	n/a	10/03/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#37 – REC, Cover Letter	n/a	26/08/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#37 – REC, Approval Letter	n/a	30/08/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#38 – REC, Cover Letter	n/a	06/10/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#38 – REC, Approval Letter	n/a	18/10/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#39 – REC, Cover Letter	n/a	15/11/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#39 – REC, Approval Letter	n/a	21/11/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#40 – REC, Cover Letter	n/a	07/02/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#40 – REC, Approval Letter	n/a	14/02/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#41 – REC, Cover Letter	n/a	05/04/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#41 – REC, Approval Letter	n/a	11/04/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#42 – REC, Cover Letter	n/a	11/04/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#42 – REC, Approval Letter	n/a	18/04/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#43 – REC, Cover Letter	n/a	22/06/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#43 – REC, Approval Letter	n/a	28/06/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#44 – REC, Cover Letter	n/a	03/07/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#44 – REC, Approval Letter	n/a	07/07/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#45 – REC, Cover Letter	n/a	25/08/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	Only applicable to relevant sites. Refer to Amendment Log for details.
SA#45 – REC, Approval Letter	n/a	15/09/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	

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SA#46 – REC, Cover Letter	n/a	04/10/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#46 – REC, Approval Letter	n/a	09/10/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – REC, Cover Letter	n/a	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – MHRA, Cover Letter	n/a	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – Notice of Amendment Form	n/a	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – CTA Application Form, Updated	n/a	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – REC, Approval Letter	n/a	13/12/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – MHRA, Approval Letter	n/a	18/12/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#47 – HRA, Approval Letter	n/a	29/12/2017	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#48 – REC, Cover Letter	n/a	19/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#48 – REC, Approval Letter	n/a	22/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#49 – REC, Cover Letter	n/a	09/02/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#49 – REC, Approval Letter	n/a	12/02/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#50 – REC, Cover Letter	n/a	23/03/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#50 – REC, Approval Letter	n/a	29/03/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#51 – REC, Cover Letter	n/a	27/04/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#51 – REC, Approval Letter	n/a	30/04/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#52 – Non-Notifiable, Non-Substantial Amendment (GDPR Transparency Statement)	n/a	30/05/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#53 – Non-Substantial Amendment Form	n/a	14/06/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#53 – HRA Approval Letter	n/a	30/06/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#54 – Non-Substantial Amendment Form	n/a	11/07/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#54 – HRA Approval Letter	n/a	13/07/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#55 – REC, Cover Letter	n/a	07/08/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#55 – REC, Approval Letter	n/a	07/08/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#56 – REC, Cover Letter	n/a	17/10/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#56 – REC, Approval Letter	n/a	24/10/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#57 – Non-Substantial Amendment Form	n/a	30/10/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#57 – HRA Approval Letter	n/a	05/11/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#58 – Non-Substantial Amendment Form	n/a	31/10/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#58 – HRA Approval Letter	n/a	05/11/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#59 – REC, Cover Letter	n/a	18/01/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#59 – REC, Approval Letter	n/a	29/01/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#60 – Non-Substantial Amendment Form	n/a	11/03/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#60 – HRA Approval Letter	n/a	21/03/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#61 – Non-Substantial Amendment Form	n/a	08/04/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#61 – HRA Approval Letter	n/a	13/05/2019	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#62 – REC, Cover Letter	n/a	02/03/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#62 – REC, Approval Letter	n/a	04/03/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#63 – Non-Notifiable, Non-Substantial Amendment (COVID-19)	n/a	23/04/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#64 – REC, Cover Letter	n/a	15/06/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#64 – REC, Approval Letter	n/a	17/06/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#65 – REC, Cover Letter	n/a	17/09/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#65 – REC, Approval Letter	n/a	17/09/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	
SA#66 – REC, Cover Letter	n/a	01/10/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#66 – REC, Approval Letter	n/a	13/10/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	

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<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>					
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS	
SA#67 – HRA/REC, Cover Letter	n/a	05/10/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#67 – HRA/REC, Approval Letter	n/a	06/10/2020	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#68 – REC, Cover Letter	n/a	10/12/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#68 – REC, Approval Letter	n/a	11/12/2020	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#69 – REC, Cover Letter	n/a	08/01/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#69 – REC, Amendment Tool	n/a	08/01/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#69 – REC, Approval Letter	n/a	12/01/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#69 – HRA, Approval Email	n/a	06/02/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#69 – MHRA, Cover Letter	n/a	08/01/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#69 – MHRA, Annex II Form	n/a	08/01/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#69 – MHRA, CTA Application Form	n/a	08/01/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#69 – MHRA, Approval Letter	n/a	05/02/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#70 – REC, Cover Letter	n/a	10/02/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>
SA#70 – REC, Approval Letter	n/a	11/02/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#70 – HRA, Approval Email	n/a	11/02/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#71 – REC, Cover Letter	n/a	25/02/2021	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#71 – REC, Approval Letter	n/a	26/02/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#71 – HRA, Approval Email	n/a	26/02/2021	Y <input type="checkbox"/> N <input type="checkbox"/>		
SA#72 – Non-Substantial Amendment	n/a	22/04/2021	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#73 – Non-Substantial Amendment	n/a	03/06/2021	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#74 – Non-Substantial Amendment	n/a	07/09/2021	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#75 – Non-Substantial Amendment	n/a	21/04/2022	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#76 – Non-Substantial Amendment	n/a	05/09/2022	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#77 – Non-Substantial Amendment	n/a	16/09/2022	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Only applicable to relevant sites. Refer to Amendment Log for details.</i>	
SA#78 – Non-Substantial Amendment	n/a	03/11/2022	Y <input type="checkbox"/> N <input type="checkbox"/>		
ARISTOTLE – Amendment Log	n/a	04/11/2022	Y <input type="checkbox"/> N <input type="checkbox"/>	Last Updated 04/11/2022	
Local SSA Application Form	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>		
R&D Approval Letters – Initial and Amendments	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>		
5. PROTOCOL AND AMENDMENTS					
Protocol	7.1	03/11/2022	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	7	16/12/2020	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	6.2	30/10/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	6.1	12/06/2018	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	6	30/11/2017	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	5.1	22/12/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	5	31/07/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	4	17/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	3.1	01/08/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	3	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	2	22/12/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	1.1	18/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol (superseded)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Protocol Version History Log	n/a	04/11/2022	Y <input type="checkbox"/> N <input type="checkbox"/>	Last Updated 04/11/2022	

PHARMACY SITE FILE CHECKLIST

SITE NAME:					
PSF – DOCUMENT VERSION CHECKLIST					
Complete 'yes' or 'no' to confirm the presence or absence of each document specified.					
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS	
6. PATIENT INFORMATION					
Patient Card – Arm A	2	30/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Card – Arm B	2	30/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Card – Arm A (<i>superseded</i>)	1.1	18/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Card – Arm B (<i>superseded</i>)	1.1	18/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Card – Arm A (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Card – Arm B (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Diary	2	17/07/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Diary (<i>superseded</i>)	1.1	30/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Diary (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
Patient Information Version History Log	n/a	02/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Last Updated 02/01/2018</i>	
7. IMP/NIMP MANAGEMENT					
7.1 RANDOMISATION					
Randomisation Procedure – Sites	3.1	25/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Rand Procedure – Sites (<i>superseded</i>)	3	25/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
Rand Procedure – Sites (<i>superseded</i>)	2	07/10/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
Rand Procedure – Sites (<i>superseded</i>)	1	27/05/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Confirmation of Randomisations - Email/Fax	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	<i>Or file note of alternate location</i>	
7.2 SUMMARY OF DRUG ARRANGEMENTS (SoDA)					
Summary of Drug Arrangements (SoDA)	5	04/07/2016	Y <input type="checkbox"/> N <input type="checkbox"/>		
SoDA (<i>superseded</i>)	4	09/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
SoDA (<i>superseded</i>)	3	27/02/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
SoDA (<i>superseded</i>)	2	15/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SoDA (<i>superseded</i>)	1	04/02/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
7.3 PACKING AND LABELLING					
Approved IMP Label – Capecitabine	3	01/02/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
Approved IMP Label – Capecitabine (<i>superseded</i>)	2	21/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Approved IMP Label – Capecitabine (<i>superseded</i>)	1	10/08/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		
7.4 DISPENSING					
Dispensing Guidelines	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>		
Master Subject List	1	26/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Master Trial Prescription	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>		
Completed Trial Prescriptions	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>		
7.5 ACCOUNTABILITY/DESTRUCTION/RETURNS					
Template Drug Accountability Log	1	31/05/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
Completed Drug Accountability Log	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>		
Site Destruction Policy	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>		
7.6 SUMMARY OF PRODUCT CHARACTERISTICS (SPC)					
SPC – Capecitabine (<i>current</i>)	n/a	10/07/2017	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	24/09/2015	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	24/12/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	23/01/2014	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	18/12/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	30/05/2013	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	15/11/2012	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	17/06/2011	Y <input type="checkbox"/> N <input type="checkbox"/>		
SPC – Capecitabine (<i>superseded</i>)	n/a	23/03/2010	Y <input type="checkbox"/> N <input type="checkbox"/>		

PHARMACY SITE FILE CHECKLIST

SITE NAME:				
PSF – DOCUMENT VERSION CHECKLIST				
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
SPC – Irinotecan (<i>current</i>)	n/a	Oct 2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
SPC – Irinotecan (<i>superseded</i>)	n/a	Apr 2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SPC – Irinotecan (<i>superseded</i>)	n/a	17/02/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
SPC – Irinotecan (<i>superseded</i>)	n/a	13/03/2010	Y <input type="checkbox"/> N <input type="checkbox"/>	
SPC – Irinotecan (<i>superseded</i>)	n/a	02/04/2009	Y <input type="checkbox"/> N <input type="checkbox"/>	
File Note – Location of SPC	n/a	28/05/2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
7.7 DRUG SAFETY				
Quarterly SUSAR Line Listing #1	22/09/2011 – 21/12/2011		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #2	22/12/2011 – 21/03/2012		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #3	22/03/2012 – 21/06/2012		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #4	22/06/2012 – 21/09/2012		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #5	22/09/2012 – 21/12/2012		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #6	22/12/2012 – 21/03/2013		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #7	22/03/2013 – 21/06/2013		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #8	22/06/2013 – 21/09/2013		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #9	22/09/2013 – 21/12/2013		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #10	22/12/2013 – 21/03/2014		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #11	22/03/2014 – 21/06/2014		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #12	22/06/2014 – 21/09/2014		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #13	22/09/2014 – 21/12/2014		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #14	22/12/2014 – 21/03/2015		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #15	22/03/2015 – 21/06/2015		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #16	22/06/2015 – 21/09/2015		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #17	22/09/2015 – 21/12/2015		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #18	22/12/2015 – 21/03/2016		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #19	22/03/2016 – 21/06/2016		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #20	22/06/2016 – 21/09/2016		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #21	22/09/2017 – 21/12/2016		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #22	22/12/2016 – 21/03/2017		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #23	22/03/2017 – 21/06/2017		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #24	22/06/2017 – 21/09/2017		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #25	22/09/2017 – 21/12/2017		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #26	22/12/2017 – 21/03/2018		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #27	22/03/2018 – 21/06/2018		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #28	22/06/2018 – 21/09/2018		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #29	22/09/2018 – 21/12/2018		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #30	22/12/2018 – 21/03/2019		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #31	22/03/2019 – 21/06/2019		Y <input type="checkbox"/> N <input type="checkbox"/>	
Quarterly SUSAR Line Listing #32	22/06/2019 – 21/09/2019		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #33	22/09/2019 – 21/12/2019		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #34	22/12/2019 – 21/03/2020		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #35	22/03/2020 – 21/06/2020		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #36	22/06/2020 – 21/09/2020		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #37	22/09/2020 – 21/12/2020		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #38	22/12/2020 – 21/03/2021		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #39	22/03/2021 – 21/06/2021		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>
Quarterly SUSAR Line Listing #40	22/06/2021 – 21/09/2021		Y <input type="checkbox"/> N <input type="checkbox"/>	<i>No SUSARs reported</i>

PHARMACY SITE FILE CHECKLIST

SITE NAME:				
PSF – DOCUMENT VERSION CHECKLIST				
<i>Complete 'yes' or 'no' to confirm the presence or absence of each document specified.</i>				
DOCUMENT NAME	VERSION	DATE	PRESENT?	COMMENTS
Quarterly SUSAR Line Listing #41	22/09/2021 – 21/12/2021		Y <input type="checkbox"/> N <input type="checkbox"/>	No SUSARs reported
Quarterly SUSAR Line Listing #42	22/12/2021 – 21/03/2022		Y <input type="checkbox"/> N <input type="checkbox"/>	No SUSARs reported
Quarterly SUSAR Line Listing #43	22/03/2022 – 21/06/2022		Y <input type="checkbox"/> N <input type="checkbox"/>	No SUSARs reported
Quarterly SUSAR Line Listing #44	22/06/2022 – 21/09/2022		Y <input type="checkbox"/> N <input type="checkbox"/>	No SUSARs reported
Safety Alert – Irinotecan Recall	n/a	24/07/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	For information only
Safety Alert – Capecitabine Drug Safety Update	n/a	23/10/2020	Y <input type="checkbox"/> N <input type="checkbox"/>	For information only
Safety Alert – Irinotecan Drug Safety Alert	n/a	22/10/2021	Y <input type="checkbox"/> N <input type="checkbox"/>	For information only
File Note – Urgent Safety Measure	Amdt 13	27/07/2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
8. INCIDENT REPORTING				
Incident Report Template	3	20/09/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Incident Report Template (<i>superseded</i>)	2	25/06/2015	Y <input type="checkbox"/> N <input type="checkbox"/>	
Incident Report Template (<i>superseded</i>)	1	15/09/2009	Y <input type="checkbox"/> N <input type="checkbox"/>	
Completed Incident Report (<i>if applicable</i>)	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
9. SITE MONITORING				
Site Initiation Slides	n/a	12/01/2018	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Initiation Slides (<i>superseded</i>)	n/a	27/06/2016	Y <input type="checkbox"/> N <input type="checkbox"/>	
Site Initiation Report	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
Monitoring Plan	3	28/08/2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
Monitoring Plan (<i>superseded</i>)	2	11/08/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Monitoring Plan (<i>superseded</i>)	1	11/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
On-Site Monitoring Visit – Site Visit Log	1	27/04/2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
Monitoring Report (<i>if applicable</i>)	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	
10. CORRESPONDENCE				
Any correspondences	n/a	n/a	Y <input type="checkbox"/> N <input type="checkbox"/>	

Please provide email address of the person to whom documents which are not available on the website should be sent to:

Checklist Completed by:

Name: _____ Role: _____ Date Completed: _____

The completed form can be returned to ctc.aristotle@ucl.ac.uk.

This is intended to support site’s own internal systems for maintaining the PSF; **therefore if the checklist is not returned to UCL CTC we will assume that documents contained within your PSF are up-to-date.**

The following are general reminders regarding maintenance of the Investigator/Pharmacy Site File:

- The folder must be stored in a secure location with appropriate/restricted access
- The documents should be filed as per index (*CTC index or site’s own index is acceptable*)
- Documents generated locally (e.g. local approvals, lab normal ranges, correspondence, etc.) must be filed in the applicable sections
- Where documents are held in an alternative location, file notes should be present to indicate this
- Up-to-date CVs & GCP training must be present for all relevant staff (*CVs should be current at the time the trial is opened, kept up-to-date and be signed & dated*)
- GCP certificates must be present (or details of course attended listed in the CV) for all staff (*All staff should have attended a course – frequency of repeat training may be dictated by the employing institution policy, or 2 yearly where the institution has no policy, and more frequently when there have been updates to the legal or regulatory requirements for conduct of clinical trials*)